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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/662,008 | 09/11/2003 | Michael Thomas Riebe | PG3411US2 | 8593 |
| 23347 | 7590 02/10/2006 | | EXAMINER | |
| GLAXOSMITHKLINE | | | EREZO, DARWIN P | |
| CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398 | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|--|--|--|--|--|--|
| | 10/662,008 | RIEBE ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Darwin P. Erezo | 3731 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of the state of the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period we failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time Till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. lely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | · | | | | |
| 1) | action is non-final. nce except for formal matters, pro- | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or | vn from consideration. | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner 11). | epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | • | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,253,762 to Britto in view of US 5,490,497 to Chippendale et al.

Britto teaches an aerosol container/inhalation device comprising a vial body containing an aerosol formulation of a medicament (fluticasone propionate; col. 2, lines 45-55) in a hydrogen-containing fluorocarbon liquid propellant (1,1,1,2-tetrafluoroethane; col. 4, lines 18-20) that is free of adjuvants; a valve 3 for dispensing a metered amount of the aerosol; wherein the valve is composed of non-fluorinated polymers (acetal; col. 4, line 57) and fluorinated polymers (PTFE; col. 4, line 67); wherein a part of the surface of the valve is in contact with the fluorinated polymer; wherein the polymer is plasma coated.

Britto teaches using fluorinated polymers blended with non-fluorinated polymers as coating for the internal surfaces of MDI device (col. 5, lines 14-22). Therefore, any coated surfaces, including the metering chamber will be comprised of a coating having a fluorinated and non-fluorinated polymers.

Britto is silent with regards to the specifics of the valve.

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Chippendale teaches a well-known valve in the art formed from plastic and comprising a valve body defining a metering chamber 2 configured to contain a metered amount of an aerosol formulation; a transfer passage 5 through which the metered amount of the aerosol formulation is able to pass from a vial body into the metering chamber; and dispensing means 6 which enables the metered amount of the aerosol formulation to be dispensed form the metering chamber.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the valve of Chippendale in the device of Britto because a valve having a metering valve, transfer passage and dispensing means is well known in the art and would be usable with the invention of Britto. Furthermore, Britto teaches the process of coating the internal surfaces of any well known canisters having a metering valve.

As to claims 2 and 13, Britto is silent with regards to the weight percentage of the fluorinated polymer. However, Britto teaches that the fluorinated polymer is coated onto the valve formed from non-fluorinated polymer. Therefore, it would have been obvious to one of ordinary skill in the art to provide a coating of about 5% weight of the valve since discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

As to claims 5 and 16, it should be noted that the claims are directed towards a product by process claim, therefore, the claim is not limited to the manipulation of the recited step, only the structure implied by the step. See MPEP 2113.

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Response to Arguments

3. Applicant's arguments filed 11/18/05 have been fully considered but they are not persuasive.

4. The applicant's main argument is directed towards the Britto reference allegedly failing to teach the metering chamber having a mixture of fluorinated polymer and non-fluorinated polymer. However, as recited in the rejections above, Britto teaches a coating for the internal surfaces of the MDI device that is comprised of a mixture of both fluorinated and non-fluorinated polymers (col. 5, lines14-22). Therefore, the metering chamber and its internal surfaces will also have said mixture of coating, and that this coating will form part of the metering chamber structure.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER